Ex parte Aburaki

dem

94-2817

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 16

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

MAILED

FEB 24 1997

PAT.&T.M. OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte SHIMPEI ABURAKI,
HARUHIRO YAMASHITA,
and TAKAYUKI NAITO

Appeal No. 94-2817
Application 07/590,621[1]

ON BRIEF

Before WINTERS, WILLIAM F. SMITH, and GRON, Administrative Patent Judges.

WINTERS, Administrative Patent Judge.

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[1] Application for patent filed September 28, 1990.

Appeal No. 94-2817
Application 07/590,621

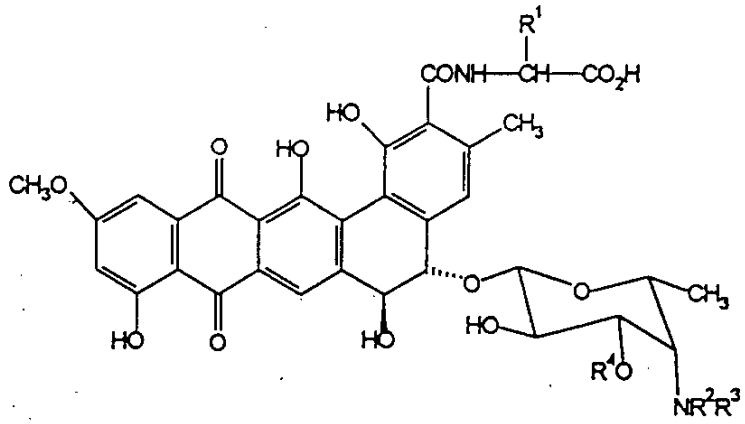
DECISION ON APPEAL

This appeal was taken from the examiner's decision refusing to allow claims 1 through 10, which are all of the claims remaining in the application.

REPRESENTATIVE CLAIMS

Claims 1 and 10, which are illustrative of the subject matter on appeal, read as follows:

1. A compound having the formula



wherein R^1 is hydrogen, methyl, or hydroxymethyl; R^2 and R^3 are independently selected from the group consisting of hydrogen and C_{1-5} alkyl; and R^4 is selected from the group consisting of β-L-xylosyl, β-D-ribosyl, α-L-arabinosyl, β-D-chinovosyl, β-D-fucosyl, and β-D-glucosyl; with the proviso that when R^1 is methyl or hydroxymethyl, and one of R^2 or R^3 is methyl, R^4 is not β-D-glucosyl; or a pharmaceutically acceptable salt thereof.

10. A pharmaceutical composition which comprises an antifungal effective amount of a compound of Claim 1 and a pharmaceutically acceptable vehicle.

THE REFERENCES

The prior art references cited and relied on by the examiner are:

Nagarajan	4,130,709	Dec. 19, 1978
Sawada et al. (Sawada)	4,973,673	Nov. 27, 1990

THE ISSUE

The issue presented for review is whether the examiner erred in rejecting claims 1 through 10 under 35 U.S.C. § 103 as unpatentable over the combined disclosures of Sawada and Nagarajan.

DELIBERATIONS

Our deliberations in this matter have included evaluation and review of the following materials:

(1) the instant specification, and all of the claims on appeal;

(2) appellants' Brief before the Board;

(3) the Examiner's Answer;

(4) the above-cited references relied on by the examiner; and

(5) the opinion and decision by another merits panel of this Board in Application Serial No. 07/589,728 (Appeal No. 94-1148 decided September 18, 1996).

On consideration of the record, including the above-listed materials, we reverse the examiner's prior art rejection.

THE REJECTION UNDER 35 U.S.C. § 103

The examiner's rejection of claims 1 through 10 under 35 U.S.C. § 103, as unpatentable over the combined disclosures of Sawada and Nagarajan, is reversed for the reasons set forth by another merits panel of this Board in Application Serial No. 07/589,728 (Appeal No. 94-1148 decided September 18, 1996). See particularly Paper No. 15, pages 5 through 7, of the related application (copy enclosed with this opinion).

OTHER ISSUES

On return of this application to the examining corps, we recommend that appellants and the examiner compare the claims in this application with those presented in Application Serial No. 07/589,728, ('728) filed September 28, 1990. Manifestly, the subject matter covered by the respective sets of claims is closely related, albeit mutually exclusive in view of the proviso in instant claim 1 that "when R^1 is methyl or hydroxymethyl, and one of R^2 or R^3 is methyl, R^4 is not β-D-glucosyl."

Note that variable R^4 in instant claim 1 may be β-D-glucosyl when R^1 is hydrogen and one of R^2 or R^3 is methyl. In that event, instant claim 1 embraces homologs of compounds defined in claim 1 of the '728 application (R^1 here is hydrogen, whereas R^1 in the '728 application is methyl). Viewing the situation in a different light, we observe that variable R^4 in instant claim 1 may be β-D-glucosyl when R^1 is methyl or hydroxymethyl and one of R^2 or R^3 is ethyl whereas the other is hydrogen or C_{2-5} alkyl. In that event, instant claim 1 embraces homologs of compounds

defined in claim 1 of the '728 application (methyl versus ethyl on the nitrogen atom attached to the sugar moiety). Furthermore, all of the compounds claimed in this application and in the '728 application are said to possess antifungal activity.

Where, as here, the respective sets of claims embrace homologs which possess antifungal activity, it would appear that the examiner should enter a "provisional" rejection on the ground of obviousness-type double patenting. See § 804 of the Manual of Patent Examining Procedure (MPEP) (6th ed., rev. 2, July 1996). Accordingly, on return of this application to the examining corps, we recommend that the examiner (1) review all of the pending claims in this application, (2) determine whether any claim defines an invention that is merely an obvious variation of an invention claimed in the '728 application, and (3) if the answer is yes, enter a "provisional" rejection on the ground of obvious-type double patenting of the involved claims.

Both appellants and the examiner will appreciate that any analysis employed in an obvious-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. § 103

obviousness determination. Again, see MPEP § 804. In obviousness rejections based on close similarity in chemical structure, the prima facie case of obviousness rises from the expectation that compounds similar in structure will have similar properties. In re Payne, 606 F.2d 303, 313, 203 USPQ 245, 254 (CCPA 1979); In re Gyurik, 596 F.2d 1012, 1018, 201 USPQ 552, 557 (CCPA 1979); In re Hoch, 428 F.2d 1341, 1344, 166 USPQ 406, 409 (CCPA 1970). Here, the respective sets of claims define compounds which are very closely related in chemical structure and which possess antifungal activity.

CONCLUSION

The examiner's rejection of claims 1 through 10 under 35 U.S.C. § 103 is reversed.

On return of this application to the examining corps, we recommend that the examiner consider entering a "provisional"

rejection on the ground of obvious-type double patenting of claims in this application over claims in the related '728 application consistent with the foregoing discussion.

REVERSED

Sherman D. Winters Administrative Patent Judge	
William F. Smith Administrative Patent Judge	BOARD OF PATENT APPEALS AND INTERFERENCES
Teddy S. Gron Administrative Patent Judge	

dem

Appeal No. 94-2817
Application 07/590,621

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INFORMATION

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today
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(2) is not binding precedent of the Board.

Paper No. 15

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte YOSUKE SAWADA,
KYOICHIRO SAITOH,
MASAMI HATORI,
TAKEO MIYAKI,
TOSHIKAZU OKI,
and KOJI TOMITA

MAILED

SEP 18 1996

PAT.&T.M. OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

Appeal No. 94-1148
Application 07/589,728[1]

ON BRIEF

Before WILLIAM F. SMITH, GRON, and WEIFFENBACH, Administrative Patent Judges.

WILLIAM F. SMITH, Administrative Patent Judge.

[1] Application for patent filed September 28, 1990.

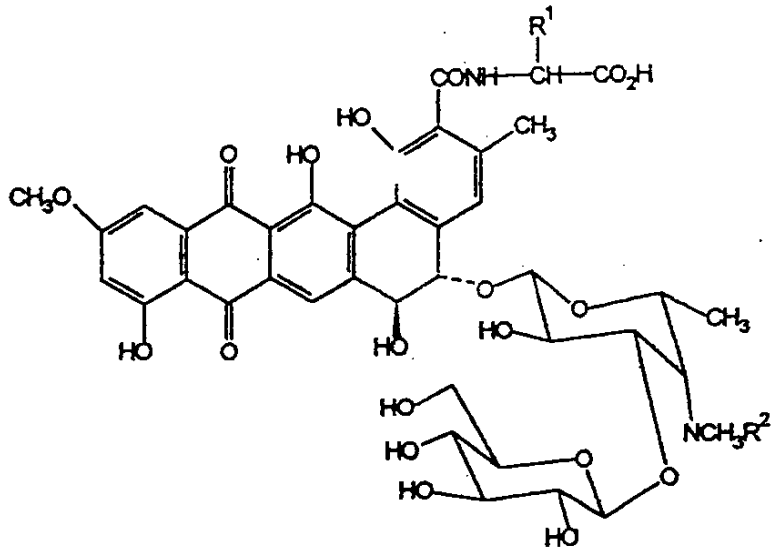
Appeal No. 94-1148
Application 07/589,728

DECISION ON APPEAL

This is an appeal from the final rejection of claims 1 through 10 and 24, all the claims remaining in the application.

Claims 1 and 24 are illustrative of the subject matter on appeal and read as follows:

1. A compound having the formula



wherein

R^1 is methyl or hydroxymethyl, and the resulting amino acid residue has the D-configuration; and

R^2 is hydrogen or C_{1-5} alkyl;

or a pharmaceutically acceptable salt thereof.

24. A pharmaceutical composition which comprises an antifungal effective amount of a compound [sic, of] Claim 1 and a pharmaceutically acceptable vehicle.

The references relied upon by the examiner are:

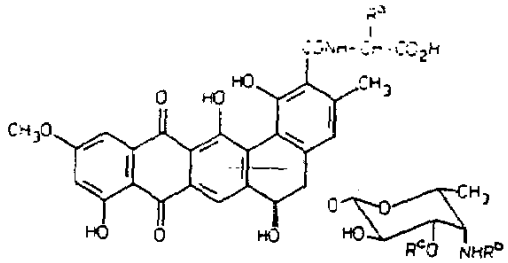
Nagarajan	4,130,709	Dec. 19, 1978
Sawada et al. (Sawada)	4,973,673	Nov. 27, 1990 (filed Nov. 10, 1988)

Claims 1 through 10 and 24 stand rejected under 35 U.S.C. § 103 as being unpatentable over Sawada in view of Nagarajan. We reverse.

BACKGROUND

The claimed compounds belong to the family of pradimicin antibiotics. As explained at page 1 of the specification:

> Pradimicins, formerly called BU-3608 antibiotics, are a family of broad spectrum antibiotics active against pathogenic yeasts and fungi. A number of pradimicin compounds obtained by fermentation of Actinomadura hibisca have been reported, and their structures are shown below as formula (I):



(I)

Pradimicin	R^a	R^b	R^c
A	CH_3	CH_3	β-D-Xylosyl
B	CH_3	CH_3	H
C	CH_3	H	β-D-Xylosyl
D	H	CH_3	β-D-Xylosyl
E	H	H	β-D-Xylosyl
FA-1	CH_2OH	CH_3	β-D-Xylosyl
FA-2	CH_2OH	H	β-D-Xylosyl

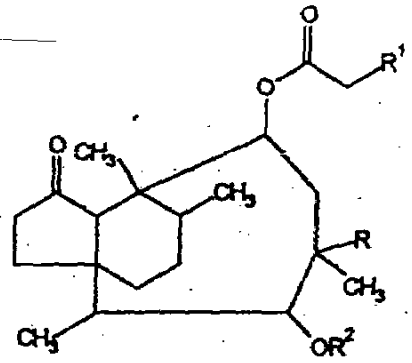
Appellants state at page 5 of the specification that:

> One aspect of the present invention provides antibiotics of [the] formula [set forth in the appealed claims] and pharmaceutically acceptable salts thereof. The compounds of the formula [set forth in the appealed claims] may be divided into subsets; one such subset provides two pradimicin antibiotics herein designated as pradimicin L and pradimicin FL which are produced by fermentation of Actinomadura verrucosospora subsp. neohibisca.

As described at page 6 pf the specification, pradimicin L is produced by cultivating either Actinomadura verrucosospora subsp. neohibisca strain R103-3 or a mutant strain derived therefrom designated strain A10019. Pradimicin FL is produced when strain R103-3 is cultured in media containing an assimilable source of D-serine.

DISCUSSION

Sawada describes certain pradimicin antibiotics including pradimicin FA-1 and FA-2. The sugar moiety of pradimicin FA-1 and FA-2 is β-D-xylosyl as opposed to the sugar moiety of the claimed compounds which is D-glucosyl. The examiner relies upon Nagarajan to establisn that one of ordinary skill in the art would have found it obvious at the time of the present invention to modify the pradimicin compounds of Sawada by replacing the xylosyl moiety with a glucosyl moiety. Nagarajan teaches pleuromutilin glycosides having the general formula



(III)

wherein R^1 is a sugar which may be, inter alia, D-xylose or D-glucose (R and R^2 are not relevant for this discussion).

Viewing these two references together, apart from appellants' disclosure of the claimed pradimicin compounds as we must, we hold that Nagarajan would not have taught or suggested to one of ordinary skill in the art to modify the compounds of Sawada in the manner needed in order to arrive at the claimed compounds. The examiner has not established that the polycyclic

antibiotics of Nagarajan are so structurally similar to the pradimicin compounds described by Sawada that Nagarajan would have suggested that its disclosed interchangeability of xylosyl and glucosyl moieties would necessarily carry over to the pradimicin compounds. The only basis we can find on this record for making the proposed substitution is hindsight.

The rejection under 35 U.S.C. § 103 is reversed.

NEW GROUND OF REJECTION UNDER
37 CFR § 1.196(b)

Claims 1, 2, 5, and 7 are unpatentable since pradimicin L is included within these claims and is a naturally occurring product in *Actinomadura verrucosospora* subsp. *neohibisca* strain R103-3. The basis of this rejection is either under 35 U.S.C. § 101 since the claims include a naturally occurring product or 35 U.S.C. § 102 as lacking novelty.

As set forth in the paragraph bridging pages 6-7 of the specification, strain R103-3 was isolated from a soil sample collected in Peru. Pradimicin L is produced by cultivating

strain R103-3 under conditions which appear to include naturally occurring conditions. Thus, as this strain exists in nature, it appears to produce the claimed compound. Significantly, claim 1 does not require that the compound be in an isolated or purified condition. Thus, these claims read upon pradimicin L as it occurs in nature.

To the extent this rejection is based upon lack of novelty, we refer the court's statement in In re Kratz, 592 F.2d 1169, 1174, 201 USPQ 71, 75-76 (CCPA 1979), that "it should be clear that an anticipation rejection in such a case is necessarily based on dual footing. First, the natural composition must inherently contain the naturally occurring compound. Secondly, the claim must be of sufficient breadth to encompass . . . the naturally occurring compound." Both conditions are met herein.

We do not include claims 3, 4, 6, and 8 through 10 in this rejection since the alkylated compounds of claim 3 do not appear to be naturally occurring (Specification, page 5, last full paragraph). Nor does it appear on this record that pradimicin FL is a naturally occurring product since appellants disclose in the

specification that this compound is obtained only when strain R103-3 is cultured in media which contains an assimilable source of D-serine. The record does not establish that D-serine is present in the environment in which strain R103-3 appears in its native state.

Nor do we include claim 24 in this rejection since it does not appear from this record that strain R103-3 is found in an environment which can reasonably be termed a pharmaceutical composition.

Any request for reconsideration or modification of this decision by the Board of Patent Appeals and Interferences based upon the same record must be filed within one month from the date of the decision. 37 CFR § 1.197. Should appellants elect to have further prosecution before the examiner in response to the new rejection under 37 CFR § 1.196(b) by way of amendment or showing of facts, or both, not previously of record, a shortened statutory period for making such response is hereby set to expire two months from the date of this decision.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

REVERSED - 37 CFR § 1.196(b)

WILLIAM F. SMITH Administrative Patent Judge	
TEDDY S. GRON Administrative Patent Judge	BOARD OF PATENT APPEALS AND INTERFERENCES
CAMERON WEIFFENBACH Administrative Patent Judge	

Appeal No. 94-1148
Application 07/589,728

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